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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MEDTRONIC AVE, INC.  
3576 UNOCAL PLACE  
SANTA ROSA, CA 95403

EXAMINER

ROBERTSON, JEFFREY

ART UNIT

PAPER NUMBER

1712

DATE MAILED: 04/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/862,710

Applicant(s)

SHAH ET AL.

Examiner

Jeffrey B. Robertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on amendments of 10/18/02 and 12/20/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-13 and 60-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-13,60-71,74 and 79 is/are rejected.
- 7) ☒ Claim(s) 72,73 and 75-78 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 14-33 have been renumbered 60-79. This application originally contained claims numbered 14-59. Therefore the newly added claims have been renumbered starting with the first consecutive claim number following the claims originally present in the application.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4-13, 60-71, 74, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al. (U.S. Patent No. 4,082,727).

For claims 1 and 60, in column 1, line 48 through column 2, line 7, Nagata teaches that an organosilicon compound (silane) is reacted with a heparin salt (biopolymer) to form an organosilicon compound with a heparin linkage, i.e. a covalent bond between the silane and the biopolymer (see also column 2, line 17). For claims 1, 10, 60, and 67 in column 5, lines 36-40, Nagata teaches that this material can be used as a coating, particularly for medical devices to impart an anticoagulant (thromboresistant) property to the medical device.

For claims 1 and 79, Nagata does not specifically teach that the product of the silane and the biopolymer is capable of binding directly to the surface of the substrate by covalent attachment of the silane to the substrate. However, the claims state that this reaction product should "be capable of" direct-covalent bonding to a substrate. This limitation is fulfilled due to the inherent properties of the reaction product, where the silane portion contains alkoxy groups. These alkoxy groups are capable of reacting with a hydroxyl-containing substrate to form a covalent bond. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

For claims 1, 4, 7, 60, 61, 64, and 70, in column 2, lines 43-51, Nagata teaches organosilicon compounds that contain an isocyanate group, which will react with a

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hydroxyl group as set forth by Nagata in column 3, lines 6-13. For claims 13 and 70, all of the organosilicon compounds listed by Nagata have a propyl group between the isocyanate functionality and the silane.

For claims 5, 6, 8, 11, 62, 63, 65, and 68, in column 1, lines 58-63, Nagata teaches that the heparin compound is a salt formed between heparin and tridodecylmethylammonium chloride.

For claims 9, 71, 66, and 74, in column 1, line 58 through column 2, line 7, Nagata teaches that the heparin complexes are soluble in organic solvents and are reacted with the silane in the organic solvent, which may be THF.

For claims 12 and 69, Nagata teaches an additive in the form of a RTV silicone rubber that is added to the heparin-silane product in column 7, lines 4-9, a film-forming agent.

For claim 60, applicant uses the transitional phrase "consisting essentially of" in the claim. Although Nagata et al. uses an additional organosilicone resin in the patent, to which the product of the silane and biopolymer is bound, the use of "consisting essentially of" does not exclude such an ingredient. There is no evidence that the addition of the organosilicone resin materially affects the basic and novel characteristics of the claimed composition, which in this case is the thromboresistant properties of the resulting treated surface. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537

F.2d 549, 551-52,190 USPQ 461, 463 (CCPA 1976) (emphasis in original). MPEP §2111.03.

4. Claims 1 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Bradley et al. (U.S. Patent No. 6,048,695).

For claims 1 and 60, in column 5, line 55 through column 6, line 47, Bradley teaches that an epoxy-containing silane is reacted with a biopolymer (DNA) and that subsequently this product is affixed to an underivatized glass surface. Bradley does not teach any other components added to this product in the Example.

#### ***Response to Arguments***

5. Applicant's arguments filed 10/18/03 have been fully considered but they are not persuasive. Applicant's arguments regarding the Nagata et al. reference are not found to be persuasive. As detailed above, the limitation "capable of directly coating a surface of a substrate by covalent attachment of said silane to said substrate" is satisfied by the inherent properties of the heparin-silane adduct. That Nagata details a reaction prior to that with an organosiloxane does not take away this inherent property. Regarding claim 60, as detailed above, the use of an organosiloxane does not appear to affect the thromboresistance of the resulting coating.

#### ***Allowable Subject Matter***

6. Claims 72, 73, and 75-78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Nagata fails to teach or suggest an isothiocyanate group as the functional group on the silane. Nagata also fails

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to teach or suggest the use of anhydrous solvents in the reaction of the silane with the biopolymer.

7. This action is made non-final by virtue of the new rejection under 35 U.S.C. 102(e) of claims 1 and 60 as being anticipated by the Bradley et al. reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey B. Robertson whose telephone number is (703) 306-5929. The examiner can normally be reached on Mon-Fri 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Dawson can be reached on (703) 308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jeffrey B. Robertson  
Examiner  
Art Unit 1712

JBR  
March 25, 2003